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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MASHACK, MARK F	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,977	ASHBY ET AL.	
	Examiner	Art Unit	
	MARK MASHACK	4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,27-33 and 40-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,27-28 and 40-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *29-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 27-28, 40-49, drawn to an apparatus to promote hemostasis, classified in class 606, subclass 213.

II. Claim 29-33, drawn to release mechanism, classified in class 604, subclass 48.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the release mechanism can be a suture loop as depicted in FIG 3 of application. The subcombination has separate utility such as a release mechanism for an embolic coil or a stent.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such

claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Brent Matthias on 4/25/2008 a provisional election was made without traverse to prosecute the invention of the apparatus to promote hemostasis, claims 1, 27-28, 40-49. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim positively recites a natural physiological condition of "the inner lumen pressure is greater than the outer lumen pressure".

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claim 28** recites the limitation "the aperture" in the body. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 40-42, 44-45** are rejected under 35 U.S.C. 102(b) as being anticipated by **Nash et al. (US 5,700,277)**.

Regarding Claim 1, Nash et al. disclose an apparatus to intervascularly promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, comprising:

a flexible plug **32** having a center, a top surface, and a bottom surface; and

a release mechanism (severance of proximal end of suture **34**; Column 8, Lines 28-33) including a hemostatic material **30** coupled to the center of the flexible plug and a resilient extension member **36** coupled to the hemostatic material opposite the flexible plug, the release mechanism positioning and releasing the flexible plug intervascularly at the blood vessel puncture site (FIG 9 and Abstract);

wherein the inner lumen pressure is greater than the outer lumen pressure.

Regarding Claim 40, Nash et al. disclose an apparatus to promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, comprising:

a flexible disk **32** to intervascularly seal a blood vessel puncture site;

a hemostatic body **30** to intravascularly seal the blood vessel puncture site; and

a connector **36** to couple the flexible disk to the hemostatic body, the connector positioned within a wall of the blood vessel puncture site;

wherein the inner lumen pressure is greater than the outer lumen pressure to forceably secure said flexible disk around the blood vessel puncture site (FIG 1-3 and Abstract).

Regarding Claim 41, Nash et al. disclose the connector **36** has a smaller diameter than a flexible disk diameter and a hemostatic body diameter **30** (FIG 1-3).

Regarding Claim 42, Nash et al. disclose a release mechanism coupled to the hemostatic body (severance of proximal end of suture **34**; Column 8, Lines 28-33).

Regarding Claim 44, Nash et al. disclose the release mechanism comprises a resilient extension member **52** coupled to the center of the hemostatic body, the resilient extension member **52** having an aperture **56** at a top (Column 6, Lines 35-55, and FIG 1-3).

Regarding Claim 45, Nash et al. disclose a suture **34** looped through the aperture **56** (FIG 1-3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 27-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al.** in view of **Haaga (US 5,254,105)**.

Regarding Claim 27, Nash et al. disclose all of the claimed limitations except for the hemostatic material being encapsulated in a biocompatible dissolvable capsule.

However, **Haaga** teaches of vascular surgical device comprising a hemostatic material being encapsulated in a biocompatible dissolvable capsule (Column 1, Line 59, - Column 2, Line 8).

All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Haaaga**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hemostatic material by encapsulating it in foam. Doing so would

provide a time-release mechanism to enhance the clot formation (Column 1, Lines 67, - Column 2, Line 5).

Regarding Claim 28, Nash et al. disclose a suture **34** looped through the aperture **62, 56** (FIG 7-9).

6. **Claim 43** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al.** in view of **Houser et al. (US 6,726,696)**.

Regarding Claim 43, Nash et al. disclose the release mechanism is a suture having a first end secured to the hemostatic body with a knot. **Nash et al.** does not disclose the attachment of the suture to the hemostatic body by an adhesive.

However, **Houser et al.** teach of the securement of a patch to a deployment device with an adhesive (Column 2, Lines 28-32).

Given the teachings of **Houser et al.**, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute one known element of adhesive for another element of a knot to yield predictable results. Doing so would secure the hemostatic body to the release mechanism.

7. **Claims 46-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al.** in view of **Hannam et al. (US 5,649,959)**.

Regarding Claims 46 and 48, Nash et al. disclose all of the claimed limitations except for the resilient extension member being made of a hemostatic material. **Nash et al.** actually teach away from the resilient extension member being made of a hemostatic material (Column 2, Lines 7-8; resilient extension member **52** is integral with the plug **32**).

However, **Hannam et al.** teach of a plug **32** and resilient extension member **68** being made of a hemostatic material (Column 7, Lines 41-54).

Nash et al. discloses the claimed invention except for the resilient extension member being made of a resilient, hemostatic material. Given the teachings of **Hannam et al.**, it would have been obvious to one having ordinary skill in the art at the time of the invention was made of a hemostatic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416. Doing so would provide a resilient temporary seal that would be absorbed within the body after a relatively short period of time (Column 7, Lines 41-54).

Regarding Claim 47 and 49, Nash et al. disclose all of the claimed libations except for encapsulating the resilient extension member with a biocompatible dissolvable capsule.

However, **Hannam et al.** teach of introducing gelatinous material such as a fibrin glue proximal the anchor (Column 4, Lines 38-57).

All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Hannam et al.**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the resilient extension member with a biocompatible dissolvable capsule. Doing so would retain the anchor in the vessel (Column 4, Lines 38-57).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Palermo (US 5,250,071), Kensey et al. (US 5,441,517), Evans et al. (US 5,728,114), Ditter (US 2005/0085852), Paprocki (US 2005/0090860), and Forsberg (US 2005/0096696)** disclose related prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 4148
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